Program Project Description:

EPA's Human Health Risk Assessment (HHRA) research program is focused on the science of assessments that inform decisions made by EPA and its partners, including states and tribes. These assessments provide the scientific basis for decisions under an array of environmental laws, including the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Toxic Substances Control Act (TSCA) and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). The current portfolio of HHRA products include:

Integrated Risk Information System (IRIS): IRIS assessments are the top tier source of toxicity information used by EPA and other health agencies to inform national standards, clean-up levels at local sites, and set advisory levels. IRIS assessments inform decisions under the CAA, CWA, SDWA, CERCLA/Superfund, and TSCA. The IRIS Program utilizes a multi-step process which provides multiple opportunities for public, stakeholder, and interagency engagement. The assessments are complex, multidisciplinary evaluations of scientific information, which are developed through a transparent and systematic process with robust, independent peer review. IRIS is the only federal program to provide toxicity values for both cancer and non-cancer effects.

Integrated Science Assessments (ISAs): Provide a concise evaluation and synthesis of science necessary to support decisions to retain or revise the National Ambient Air Quality Standards (NAAQS) for six criteria air pollutants (particulate matter, ozone, lead, sulfur oxides, nitrogen oxides, and carbon monoxide) as required every five years by sections 108(a)(2) and 109(d)(1) of the Clean Air Act.[1] ISAs also inform the benefit-cost analyses that support the regulations designed to allow states and local areas to meet the NAAQS.

***Community and Site-specific Risk*:** Develop Provisional Peer-Reviewed Toxicity Values (PPRTVs) and exposure assessment tools to help inform EPA's timely response to contaminated Superfund and hazardous waste sites, as required by the CERCLA.[2] PPRTVs are typically developed for data poor chemicals for which no IRIS value exists.

Research to Advance Risk Assessment Methods: Develop tools and methods that support the scientific advances in assessments. This includes research to incorporate non-animal testing data into assessments. It also includes research on assessment methods for emerging contaminants such as perfluorinated compounds and biotechnologies.

The HHRA program anticipates developing new assessment approaches by means of an expanded product line to enhance rapid response and screening capabilities and to augment toxicity value derivation procedures for health assessments.

Recent accomplishments include:

Improvements to IRIS

- Implemented systematic review to ensure IRIS evaluations are complete, unbiased, reproducible and transparent;
- Developed fit-for-purpose products to ensure IRIS remains responsive to stakeholders/partners;
- Responded to GAO: the 2017 GAO High Risk report noted significant improvement in their high risk criteria ratings specific to the IRIS Program; and,
- Planned a NAS review of the IRIS program in February, 2018. NAS will issue a consensus report within 6 months.

[1] https://www.epa.gov/clean-air-act-overview/clean-air-act-title-i-air-pollution-prevention-and-control-parts-through-d#ia
[2] See 42 U.S.C. Sec. 9601 et seq.:
http://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter103&edition=prelim#9601_5_target

Examples of HHRA Deliverables

To support TSCA, a systematic review protocol as well as a draft document containing a preliminary hazard evaluation for Hexabromocyclododecane (HBCD) was delivered to the Agency's Chemical Safety and Pollution Prevention program to support their risk evaluation. HBCD is one of the first ten chemicals designated to be evaluated under TSCA.

Final ***IRIS assessments*** for Ethylene Oxide, and Benzo(a)pyrene were completed; and draft IRIS assessments for Ethyl tert-Butyl Ether (ETBE), and tert-Butyl Alcohol (TBA) were released to the Science Advisory Board (SAB) for independent, external peer review.

ISA chapters were developed for two final Integrated Review Plans (IRPs): one to support the primary and secondary NAAQS review for particulate matter and another to support the secondary NAAQS review for oxides of nitrogen and sulfur. In addition, the final ISA for Oxides of Sulfur – Health Criteria to support the primary NAAQS for SO2 was issued in December 2017.

HHRA continues to provide ongoing technical support for EPA's human health and ecological risk assessment program, delivered 12 high priority ***PPRTV assessments*** in FY 2017, and is planning to deliver a similar number by the end of FY 2018.

FY 2019 Activities and Performance Plan:

Work in this program supports Goal 3/Objective 3.3 to refocus the EPA's robust research and scientific analyses. The HHRA program's work in FY 2019 will focus explicitly on efforts integral to achieving the Administrator's priorities and informing the Agency's implementation of key environmental regulations. Examples of this work include:

- **Support the Agency's Implementation of TSCA:** Provide scientific products and support required for TSCA implementation to the Agency's Chemical Safety and Pollution Prevention program. This will include support for risk evaluations of the first 10 TSCA chemicals (Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, 81 FR 91927), through to completion in FY 2019, as well as any additional chemicals identified for the pipeline of TSCA risk evaluations [TSCA section 6(b)(2)]. The program will continue its efforts to maintain and improve support of TSCA implementation.
- **Support the Agency's Implementation of the Safe Drinking Water Act:** Provide research and technical support to the Water program. Specifically, in support of the Safe Drinking Water and Clean Water Acts, HHRA will focus on evaluating health impacts from exposure to known and emerging, chemical and biological contaminants under the authorities of SDWA.
- **Support the Agency's Implementation of the Clean Air Act:**
  - Provide the scientific products and support to the Agency's Air and Radiation program to conduct Risk and Technology Reviews under Title III of the Clean Air Act.
  - Provide ISAs to support decisions to retain or revise the NAAQS for six criteria air pollutants as required every five years by the Clean Air Act. ISAs also inform analyses by state and local officials, including benefit-cost analyses, to support implementation of air quality management programs.

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- **Targeted support for Programs, Regions, States, and Tribes:** Develop a portfolio of products that optimize the application of best available science and technology, with an increased focus on the specific decision needs. These more targeted assessments will promote greater throughput,

and will be shaped for use by several partners, including the states, tribes, other federal agencies, and EPA's national and regional program offices.

- **Support Superfund:** Provide IRIS, Provisional Peer-Reviewed Toxicity Values (PPRTVs), and advanced exposure assessment tools, as well as provide technical support to help inform EPA's clean-up decisions at contaminated Superfund, Brownfields, and hazardous waste sites, as required by RCRA and CERCLA.
- **Human and Ecological Risk Assessments:** Provide localized technical assistance and scientific expertise on human and ecological risk assessments to states, tribes, regions and programs. This includes direct support in cases of emergencies and other rapid response situations.

The Agency is currently reviewing IRIS to ensure it supports the Agency's highest public health decision-making, and its role in supporting the TSCA program, while continuing to support all of EPA's programs.

Performance Measure Targets:

The table above reflects HHRA's annual performance measures. The EPA uses these measures to assess our effectiveness in delivering needed products and outputs to clients (decision-makers, states, and local governments).

ORD's state engagement program is designed to inform states about ORD's research programs and role within EPA, and to enable ORD to better understand the science needs of state environmental agencies. Key partners at the state level include the Environmental Council of the States (ECOS), with its Environmental Research Institute of the States (ERIS) and the Interstate Technology and Regulatory Council (ITRC), the Association of State and Territorial Health Officials (ASTHO), as well as state media associations such as the Association of State and Territorial Solid Waste Management Officials (ASTSWMO).

EPA has established a standing subcommittee under EPA's Board of Scientific Counselors (BOSC) for the Chemical Safety for Sustainability and Human Health Risk Assessment National Research Programs that will be utilized to evaluate the HHRA program as part of its performance and provide feedback to the Agency. EPA will meet regularly with the BOSC for input on topics related to research program design, science quality, innovation, relevance and impact. This includes advising EPA on developing its strategic research direction and Strategic Research Action Plans for FY 2019-2022.

EPA collaborates with several science agencies and the research community to assess our research performance, such as the National Institutes of Health, the National Science Foundation, the Department of Energy (DOE), and the United States Department of Agriculture (USDA). The Agency also will work with the White House's Office of Science and Technology Policy. EPA supports the interagency Science and Technology in America's Reinvestment—Measuring the Effect of Research on Innovation, Competitiveness and Science (STAR METRICS) effort. This interagency effort is helping EPA to more effectively measure the impact federal science investments have on society, the environment, and the economy.[3]

FY 2019 Change from FY 2018 Annualized CR (Dollars in Thousands):

- (+$937.0) This change to fixed and other costs is an increase due to the recalculation of base workforce costs due to adjustments in salary, essential workforce support, and benefit costs.

[3] STAR METRICS, https://www.starmetrics.nih.gov/

- (-$13,907.0 /-65.5 FTE)
  - This significantly reduces HHRA's ability to develop assessments to support Agency's decisions. This will not only impact the number of FTE's but also the composition of the multidisciplinary teams assembled to address the needs of complex Agency decisions.
  - It will also diminish HHRA's ability to provide daily technical support to Programs, Regions, States, and Tribes, including during emergencies and urgent circumstances.
- (-$2,317.0 /-15.2 FTE) Resources are being realigned to the Superfund appropriation within this program project for IRIS.

Statutory Authority:

CAA Amendments, 42 U.S.C. 7403 et seq. - Sections 103, 108, 109, and 112; CERCLA (Superfund, 1980) Section 209(a) of Public Law 99-499; CWA Title I, Sec. 101(a)(6) 33 U.S.C. 1254 – Sec 104 (a) and (c) and Sec. 105; ERDDA 33 U.S.C. 1251 – Section 2(a); FIFRA (7 U.S.C. s/s 136 et seq. (1996), as amended), Sec. 3(c)(2)(A); FQPA PL 104-170; SDWA (1996) 42 U.S.C. Section 300j-18; TSCA (Public Law 94-469): 15 U.S.C. s/s 2601 et seq. (1976), Sec. 4(b)(1)(B), Sec. 4(b)(2)(B).